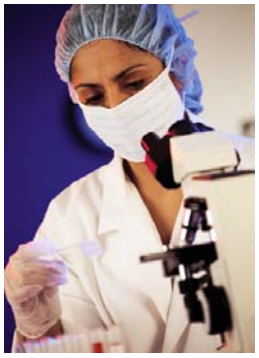
News and Resources from the National Institutes of Health

Kidney Disease Research Updates

National Kidney and Urologic Diseases Information Clearinghouse Spring 2012

Possible Cause of FSGS, Devastating Kidney Disease, Discovered

Focal segmental glomerulosclerosis (FSGS) is a common cause of kidney failure, affecting both children and adults. FSGS is marked in its early stages by proteinuria and can be found in both native and transplanted kidneys. Treatments for FSGS have been limited as the causes of the disease have not been fully understood. However, a team of researchers supported in part by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has made a discovery that might yield new treatments and help assess risk in transplantation.



Jochen Reiser, M.D., and colleagues at the University of Miami Miller School of Medicine published a paper in *Nature Medicine* that may shed light on the pathogenesis of FSGS. Researchers have long known that FSGS recurs in about one third of patients who receive a transplant, a sign that the cause of the disease resides in the blood circulating through the kidney rather than in the kidney itself. With funding from NIDDK, Dr. Reiser and colleagues discovered that about two-thirds of people with FSGS have elevated blood levels of a substance called serum soluble urokinase receptor (suPAR). The elevated levels of this factor are not found in people with other glomerular diseases.

FSGS affects kidney function by attacking the glomeruli, the tiny units within the kidney where blood is filtered. There are approximately 1 million glomeruli in each kidney. Each glomerulus includes blood vessels with specially modified walls which serve as the filter. Podocytes are the cells in the vessel wall that regulate which elements of the blood pass through the filter membrane into the urine. When the kidneys are healthy, protein remains in the blood while wastes and salts pass through the membrane.

Using mouse models and a bank of patient samples, the research team found that circulating suPAR activates a protein on the surface of the podocytes. This disruption causes

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NIDDK
National Institute of Diabetes and Digestive and Kidney Diseases

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"This work shows convincingly and for the first time the existence of a circulating FSGS factor. The discovery allows us to potentially derive new therapies that are aimed at removing this protein from the blood, which will give rise to better therapies very soon."

Jochen Reiser, M.D.
University of Miami Miller School of Medicine

protein from the blood to pass through the membrane into the urine. The kidneys become scarred and an FSGS-like disease develops in the mouse. Dr. Reiser and colleagues speculate that reducing the amount of suPAR in the blood by plasmapheresis—a process that filters protein from the blood—might prevent FSGS from developing in the transplanted kidney. The research team also noted that another treatment strategy might be to interfere with the interaction between the suPAR in the blood and the protein on the surface of the membrane cells.

"This is an exciting discovery," said Reiser in an online video, "because it allows us to track the levels of suPar in the blood of patients with FSGS. This work shows convincingly and for the first time the existence of a circulating FSGS factor. The discovery allows us to potentially derive new therapies that are aimed at removing this protein from the blood, which will give rise to better therapies very soon. Overall it will help us to better stratify risk in transplantation cases and will also help us to engage in more and better research in the future." As with all research, additional work is necessary to confirm and further understand the findings before they can be applied to patient care.

The National Kidney and Urologic Diseases Information Clearinghouse, part of the NIDDK, offers fact sheets and easy-to-read booklets about the kidneys, kidney disease, and treatments for kidney failure. For more information or to obtain copies, visit *www.kidney.niddk.nih.gov.* ■

Would you like to know more about NIDDK-supported research?

The National Institutes of Health (NIH) provides access to a variety of reporting tools, reports, data, and analyses of NIH research activities at the Research Portfolio Online Reporting Tools (RePORT) website, *www.projectreporter.nih.gov/reporter.cfm.* One of the tools available is RePORT Expenditures and Results (RePORTER), which allows users to search a repository of NIH-funded research projects and access and download publications and patents resulting from NIH funding. ■

Kidney Disease
Research Updates

Kidney Disease Research Updates, an email newsletter, is sent to subscribers by the National Kidney and Urologic Diseases Information Clearinghouse (NKUDIC). The newsletter features news about kidney disease, special events, patient and professional meetings, and new publications available from the NKUDIC and other organizations.

You can read or download a PDF version or subscribe to the newsletter at *www.kidney.niddk.nih.gov/about/newsletter.aspx*.

Executive Editor: Andrew S. Narva, M.D., F.A.C.P.

Dr. Narva is the director of the National Kidney Disease Education Program (NKDEP) within the National Institute of Diabetes and Digestive and Kidney Diseases. Prior to joining the NKDEP in 2006, he served as chief clinical consultant for nephrology and director of the Kidney Disease Program for the Indian Health Service. He has served as a member of the Medical Review Board of End-Stage Renal Disease Network 15, the NKF Kidney Early Evaluation Program, and on the Steering Committee for the National Quality Forum Renal Endorsement Maintenance Project. Dr. Narva serves on the Expert Panel on Clinical Guidelines on High Blood Pressure (JNC 8), the NKF KDOQI Work Group on Diabetes in Chronic Kidney Disease, and the Working Group on CKD, International Federation of Clinical Chemistry and Laboratory Medicine.

NIH Researchers Identify Elusive Connection Between CKD and CVD

People with chronic kidney disease (CKD) are more likely to die from a heart attack or stroke than they are to progress to kidney failure requiring dialysis or a transplant. It is well established that CKD is associated with an increased risk of cardiovascular disease (CVD).

"While many factors are involved in the complex pathogenesis of LVH, the results of this study indicate that FGF23 is one contributing molecular mediator."

Myles C. Wolf, M.D., M.M.Sc.
University of Miami, and colleagues

Until recently, however, researchers have not been able to identify the precise mechanism that would explain the connection between the two diseases. But a recent study led by researchers at the University of Miami and funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health indicates that elevated levels of a certain hormone partially explain the connection between CKD and CVD. Results are in the November 1, 2011, issue of the *Journal of Clinical Investigation.*

In a previous study of patients beginning hemodialysis for treatment of kidney failure, individuals with elevated blood levels of the hormone fibroblast growth factor 23 (FGF23) were found to be at nearly six times greater risk of death compared to those with lower levels. However, the hormone had not been tested in the much larger population of patients with less advanced CKD. Then, in a study reported in the June 2011 *Journal of the American Medical Association,* researchers reported that patients with CKD and high levels of FGF23 are at three times higher risk of death compared to patients with lower levels of the hormone.

In the study reported in November, senior study author Myles Wolf, M.D., M.M.Sc., and colleagues at the University of Miami found that FGF23 plays a direct role in increasing the risk of CVD in people with CKD. Researchers have known that the presence of a high level of FGF23 is associated with the presence of left ventricular hypertrophy (LVH), enlargement of the left pumping chamber in the heart, an important mechanism in CVD. But it was not known whether FGF23 was the specific cause of LVH. Wolf and colleagues injected FGF23 into the bloodstream or into the heart of wild-type mice and found that these mice developed LVH. Furthermore, injecting an FGF23 blocker into mice with chronic kidney disease prevented the development of LVH.

The researchers also measured FGF23 levels in baseline plasma samples from thousands of individuals with CKD who underwent echocardiography 1 year later. The median plasma FGF23 level was more than three-fold greater than that in previous studies of predominantly non-CKD populations. Furthermore, the people with the largest mass on the left side of the heart corresponded with the people who had the highest levels of FGF23. Even after adjusting for several factors—such as weight, smoking, systolic blood pressure, and history of cardiovascular disease—FGF23 was still found to be an independent risk factor for LVH.

Furthermore, Wolf and colleagues determined that elevated FGF23 was associated with increased risk of new-onset LVH in CKD. The researchers followed 411 participants with CKD and normal sized hearts, measuring levels of FGF23 in their blood at baseline. After 3 years, 84 participants developed new-onset LVH. The researchers found that the participants with the highest levels of FGF23 had the greatest risk of

Connection Between CKD and CVD, continued on page 6

Secrets of Kidney Development Revealed in Zebrafish Research

With support from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), researchers Rebecca Wingert, Ph.D., and Alan Davidson at the Center for Regenerative Medicine, Massachusetts General Hospital, have unraveled the sequence of steps in the development of the nephron, a microscopic structure in the kidneys where blood is filtered. Millions of nephrons in each kidney work collectively to remove waste and extra water from the blood in vertebrate animals. Studying zebrafish as a genetic model organism, Wingert and Davidson used genetic and chemical genetic models of retinoic acid (RA) deficiency to discover that RA modulates the formation of rostral progenitor formation.

"Our results suggest a model whereby RA patterns the early field of nephron progentitors, with subsequent factors like inx3b acting to refine later progenitor subdomains and ensure activation of segment-specific gene programs."

Rebecca Wingert, Ph.D., and Alan Davidson
Center for Regenerative Medicine, Massachusetts General Hospital

In a paper published in *Developmental Dynamics,* Wingert and Davidson explain that kidney nephrons are composed of proximal and distal tubule segments that perform unique roles in excretion. The sequence of events that differentiates the segments as the nephron develops is not well understood. Wingert and Davidson used the zebrafish pronephros, an early version of the developing nephron, to study how the nephron divides into segments with different functions. "We found that zebrafish nephron progenitors undergo elaborate spatiotemporal expression changes of many genes before adopting a segment fate," wrote Wingert and Davidson in their article. At first, the nephron progenitors divide into two domains. The domains are then further divided into separate nephron segments.

At this point, the models of RA deficiency demonstrate how RA modulates rostral progenitor formation. To study the further development of the nephron, Wingert and Davidson knocked down the irx3b transcription factor and found it regulates proximal tubule segment size and distal segment differentiation. Wingert and Davidson conclude, "Our results suggest a model whereby RA patterns the early field of nephron progentitors, with subsequent factors like irx3b acting to refine later progenitor subdomains and ensure activation of segment-specific gene programs."

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Intensive Therapy Halves Kidney Disease in Type 1 Diabetes

NIH-funded Study Shows Long-term Benefits

Adapted from NIH News

Controlling blood glucose early in the course of type 1 diabetes yields huge dividends, preserving kidney function for decades. The new finding from a study funded by the National Institutes of Health was published in the *Archives of Internal Medicine*.

"Achieving near-normal glucose levels in type 1 diabetes can be challenging. But our study provides strong evidence that reinforces the benefits of reaching the goal as early as possible to slow or prevent kidney disease and other complications."

Ian H. de Boer, M.D.
University of Washington, Seattle

Compared to conventional therapy, near-normal control of blood glucose beginning soon after diagnosis of type 1 diabetes and continuing an average six and a half years reduced by half the long-term risk of developing kidney disease, according to the Diabetes Control and Complications Trial (DCCT) and Epidemiology of Diabetes Interventions and Complications (EDIC) Research Group. The risk of kidney failure was also halved, but the difference was not statistically significant, perhaps due to the relatively small total number of patients who reached that stage of the disease.

Participants entered the DCCT on average six years after onset of diabetes when complications of diabetes were absent or very mild. Half aimed for near-normal glucose control (intensive therapy) and the others received what was then standard glucose control. After an average 22-year follow-up, 24 in the intensive group developed significantly reduced kidney function and 8 progressed to kidney failure requiring dialysis or transplantation. On conventional therapy, 46 developed kidney disease, with kidney failure in 16.

The landmark DCCT demonstrated that intensive control reduced early signs of eye, kidney and nerve damage and is the basis for current guidelines for diabetes therapy. However, the initial kidney findings were based on reductions in urine protein, a sign of kidney damage but not a measure of kidney function. Preventing loss of kidney function and reducing kidney failure had not been proven.

Since the DCCT ended in 1993, all participants have tried to maintain excellent diabetes control and have achieved similar glucose levels. The new finding emphasizes the importance of good control of type 1 diabetes soon after diagnosis.

"Achieving near-normal glucose levels in type 1 diabetes can be challenging. But our study provides strong evidence that reinforces the benefits of reaching the goal as early as possible to slow or prevent kidney disease and other complications," said first author Ian H. de Boer, M.D., a kidney specialist at the University of Washington, Seattle.

The DCCT, conducted from 1983 to 1993 in 1,441 people with type 1 diabetes, found that intensive glucose control was superior to conventional control in delaying or preventing complications overall. EDIC continues to follow 1,375 DCCT participants to determine the long-term effects of the therapies beyond the initial treatment period. Other reports have bolstered support for intensive treatment to reduce the risk of heart disease, stroke and eye and nerve damage associated with diabetes.

"The DCCT and EDIC studies illustrate the value of long-term studies. The full benefit of treatment may not be seen for decades, especially for complications of diabetes, such as kidney disease, which can progress slowly but

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developing LVH, even in patients with normal blood pressure.

"While many factors are involved in the complex pathogenesis of LVH, the results of this study indicate that FGF23 is one contributing molecular mediator," concluded Wolf and colleagues.

The findings are based on data from 3,879 racially diverse participants with CKD who enrolled in the NIDDK-supported, multi-center, observational Chronic Renal Insufficiency Cohort (CRIC) Study between June 2003 and September 2008. During a median follow up period of 3.5 years, 266 patients died and 410 developed kidney failure.

An estimated 23 million American adults have CKD, and nearly 400,000 people in the United States and 2 million worldwide depend on dialysis to treat kidney failure. CKD costs the nation $57.5 billion per year, or roughly 23 percent of total Medicare expenditures, and end-stage renal disease carries a cost of $39.5 billion.

This research was also supported by the National Institutes of Health's National Center for Research Resources.

For more information about the CRIC Study, visit *http://archives.niddk.nih.gov/patient/cric/cric.aspx*.

The National Kidney Disease Education Program, part of the NIDDK, offers health information about CKD. For more information, visit *www.nkdep.nih.gov*. ■

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have devastating consequences," said Griffin P. Rodgers, M.D., director of the NIH's National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), which oversaw the research. "Not only has NIH-sponsored research shown the benefits of early glucose control, it has provided new tools to help people with type 1 diabetes achieve that control and live longer and healthier lives."

The DCCT compared intensive to conventional control of blood glucose in people with type 1 diabetes. At the time, conventional treatment was one or two insulin injections a day with daily urine or blood glucose testing. Participants randomly assigned to intensive treatment were asked to keep glucose levels as near normal as possible. That meant trying to keep hemoglobin A1c (A1C) readings at 6 percent or less with at least three insulin injections a day or an insulin pump, guided by frequent self-monitoring of blood glucose. (A1C reflects average blood glucose over the previous two to three months.)

Nearly 26 million Americans have diabetes. In adults, type 1 diabetes accounts for 5 to 10 percent of all diagnosed cases of the disease. Formerly called juvenile-onset or insulin-dependent diabetes, type 1 diabetes develops when the body's immune system destroys pancreatic beta cells, the only cells in the body that make the hormone insulin that regulates blood glucose. Type 1 diabetes usually arises in children and young adults but can occur at any age. Management involves keeping blood glucose levels as close to normal as possible with three or more insulin injections a day or treatment with an insulin pump, careful monitoring of glucose, and close attention to diet and exercise.

The National Kidney Disease Education Program, part of the NIDDK, offers health information about CKD. For more information, visit *www.nkdep.nih.gov*. ■

Desensitization Protocol Increases Survival in Kidney Recipients

More than 90,000 people with end-stage renal disease are on the waiting list for a kidney transplant. Of these, more than 20,000 are sensitized to human leukocyte antigen (HLA) so that their bodies will reject all but the most compatible kidneys, increasing their time on the waiting list.

"These data provide evidence that desensitization protocols may help overcome incompatibility barriers in live-donor renal transplantation and provide a substantial survival benefit for those who are offered this new modality."

Robert A. Montgomery, M.D.
The Johns Hopkins University School of Medicine, and colleagues

A team of researchers at The Johns Hopkins University School of Medicine—led by Robert A. Montgomery, M.D., and supported in part by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)—has developed a protocol that desensitizes a potential kidney recipient to a specific live-donor's HLA.

The protocol included a process—plasmapheresis—that filters the blood of the kidney recipient to deplete it of donor-specific anti-HLA antibodies. Another step in the protocol was to administer low-dose intravenous immunoglobulin. Finally, a kidney from the live-donor was transplanted.

The study included three groups: (1) the treatment group, i.e., the desensitized kidney recipients, (2) a control group from the waiting list that received dialysis only, and (3) another control group that underwent either dialysis or HLA-compatible (conventional) transplantation. The treatment group included 211 patients treated from 1998 to 2009. The control groups were carefully matched to the treatment group. For each member of the treatment group, five matching individuals were selected from the kidney transplant waiting list. The matching individuals were then divided into the two control groups.

The results of the study were published in *The New England Journal of Medicine.* What Montgomery and colleagues found was that the desensitization and transplantation protocol bestowed a far better survival rate over the patients who received dialysis only or who received either dialysis or conventional transplantation. While the differences were small in the first year, they increased substantially as the years passed. After 8 years, the desensitized treatment group had an 80 percent survival rate. Only 30 percent of the dialysis-only group survived 8 years. The dialysis-or-transplant group had a somewhat better 49 percent survival rate.

While adding plasmapheresis increases the cost of treatment, prolonged dialysis is much more expensive in the long run. Montgomery and colleagues concluded, "These data provide evidence that desensitization protocols may help overcome incompatibility barriers in live-donor renal transplantation and provide a substantial survival benefit for those who are offered this new modality."

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Complications of Chronic Kidney Disease Occur Earlier in Children

From NIH News

In what may lead to a shift in treatment, the largest prospective study of children with chronic kidney disease (CKD) has confirmed some experts' suspicions that complications occur early. The findings suggest the need for earlier, more aggressive management of blood pressure, anemia and other problems associated with kidney disease, according to Dr. Marva Moxey-Mims, M.D., a pediatric kidney specialist at NIDDK.

"Considering that a lot of kids may not be diagnosed with kidney disease until they are at that lower level of kidney function, this is important. Even above a GFR of 50, some of the abnormalities are already there."

Marva Moxey-Mims, M.D.
NIDDK

Results of the Chronic Kidney Disease in Children (CKiD) Study are in the September 2011 issue of the *Clinical Journal of the American Society of Nephrology*.

Growth failure, metabolic abnormalities and cardiovascular disease risk factors such as high blood pressure occur even at a glomerular filtration rate (GFR) of 50 milliliters per minute in children with CKD. GFR is a measure of kidney function, and a GFR of 50 is approximately half of normal function. Despite therapy, these complications increased in prevalence two- to four-fold with decreasing GFR, concluded the study, funded primarily by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health.

Dr. Moxey-Mims noted that many experts previously thought that complications of kidney disease, such as anemia, acidosis and elevated potassium and phosphate, did not usually happen until kidney function was much worse than a GFR of 50.

"Metabolic abnormalities and cardiovascular disease risk factors have rarely been systematically assessed in children with CKD," said Dr. Susan Furth, a researcher at The Children's Hospital of Philadelphia and lead study author. "We sought to identify the point along the GFR spectrum at which various common consequences of CKD become more prevalent." Metabolic abnormalities include high phosphorus and potassium levels, acidosis (too much acid in the blood), anemia and high cholesterol.

"Considering that a lot of kids may not be diagnosed with kidney disease until they are at that lower level of kidney function, this is important. Even above a GFR of 50, some of the abnormalities are already there," Dr. Moxey-Mims said. "Indeed, they get worse as kidney function drops, but the study shows that issues start to develop sooner than many thought."

Moxey-Mims added that the findings support what some in the pediatric nephrology community have known anecdotally. "It's showing us little snippets of things that are putting kids at risk among those who we previously thought were not at risk for the morbidities of chronic kidney disease," she said. "Now we know that maybe those who are down to a GFR of 50 are the kids to start watching more closely. That's the main lesson from these findings."

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Kidney Dopamine Found to Regulate Blood Pressure, Life Span

The importance of dopamine as a neurotransmitter in the brain and throughout the body is well appreciated. However, researchers at the Vanderbilt University School of Medicine, led by Ming-Zhi Zhang, M.D., and Raymond Harris, M.D., have discovered yet another essential role of dopamine synthesized in the kidney.

"These results demonstrate the importance of the intrarenal dopaminergic system in salt and water homeostasis and blood pressure control."

Ming-Zhi Zhang, M.D.
Vanderbilt University School of Medicine, and colleagues

Using knockout mice lacking the amino acid decarboxylase, a key element in the synthesis of dopamine inside the kidney, the Vanderbilt researchers sought to distinguish the role of intrarenal dopamine from extrarenal dopamine.

The researchers' findings showed that dopamine synthesized in the kidney regulates blood pressure. The knockout mice exhibited increased expression of nephron sodium transporters and decreased excretion of salt in the urine as well as decreased urine production, resulting in salt-sensitive hypertension. The mice had increased renin expression and other related alterations to the renin-angiotensin system associated with renal injury.

Perhaps most important, the knockout mice had a shorter life span than that of wild-type mice. In other words, dopamine synthesized in the kidney has a positive relationship with lifespan. Zhang and colleagues concluded, "These results demonstrate the importance of the intrarenal dopaminergic system in salt and water homeostasis and blood pressure control. Decreasing intrarenal dopamine … results in the development of hypertension and a dramatic decrease in longevity." ■

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CKiD is a multi-center, prospective study of children and teenagers ages 1 to 16 years with mild to moderate impairment of kidney function, defined as an estimated GFR between 30 and 90. Forty-eight sites in the United States and two in Canada are following 586 children. There are two clinical coordinating centers, at Children's Mercy Hospital at the University of Missouri-Kansas City School of Medicine, and The Children's Hospital of Philadelphia at the University of Pennsylvania. The central laboratory is at the University of Rochester, N.Y., and the data coordinating center is at the Johns Hopkins Bloomberg School of Public Health, Baltimore. The ongoing CKiD study aims to determine risk factors for declining kidney function and to understand how the decline affects cognitive function, behavior, growth failure and the risk for cardiovascular disease.

For more information on the CKiD Study (NCT00327860) visit *www.clinicaltrials.gov*. Learn more about kidney disease at *www.nkdep.nih.gov*. General information about children and clinical studies can be found at: *www.nhlbi.nih.gov/childrenandclinicalstudies*.

Additional support was provided by the National Institute of Neurological Disorders and Stroke, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Heart, Lung, and Blood Institute, all at the NIH. ■

New NIH Center Will Translate Research Discoveries into New Drugs, Devices

From NIH News

In a move to re-engineer the process of translating scientific discoveries into new drugs, diagnostics, and devices, the National Institutes of Health has established the National Center for Advancing Translational Sciences (NCATS). The action was made possible by Congress' approval of a fiscal year 2012 spending bill and the president's signing of the bill, which includes the establishment of NCATS with a budget of $575 million.

NCATS will serve as the nation's hub for catalyzing innovations in translational science. Working closely with partners in the regulatory, academic, nonprofit, and private sectors, NCATS will strive to identify and overcome hurdles that slow the development of effective treatments and cures.

"Congressional support for the National Center for Advancing Translational Sciences marks a major milestone in mobilizing the community effort required to revolutionize the science of translation," said NIH Director Dr. Francis S. Collins, M.D., Ph.D. "Patients suffering from debilitating and life threatening diseases do not have the luxury to wait the 13 years it currently takes to translate new scientific discoveries into treatments that could save or improve the quality of their lives. The entire community must work together to forge a new paradigm, and NCATS aims to catalyze this effort."

A prime example of the type of innovative projects that will be led by NCATS is the new initiative between NIH, the Defense Advanced Research Projects Agency, and the U.S. Food and Drug Administration to develop cutting-edge chip technology. This new technology will allow researchers to screen for safe and effective drugs far more swiftly and efficiently than current methods. A great deal of time and money can be saved testing drug safety and effectiveness much earlier in the process.

To meet the goals of NCATS, NIH is reorganizing a wide range of preclinical and clinical translational science capabilities within NIH into an integrated scientific enterprise with new leadership and a bold new agenda. While the effort to recruit an NCATS director continues, organizational changes and realignment of resources will move forward under the leadership of Acting Director Thomas R. Insel, M.D., and Acting Deputy Director Kathy Hudson, Ph.D. Dr. Insel is the director of the National Institutes of Mental Health and Dr. Hudson is the deputy director for science, outreach, and policy at the National Institutes of Health.

The following programs will comprise NCATS:

- Bridging Interventional Development Gaps, which makes available critical resources needed for the development of new therapeutic agents

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- Clinical and Translational Science Awards, which fund a national consortium of medical research institutions working together to improve the way clinical and translational research is conducted nationwide
- Cures Acceleration Network, which enables NCATS to fund research in new and innovative ways
- FDA-NIH Regulatory Science, which is an interagency partnership that aims to accelerate the development and use of better tools, standards and approaches for developing and evaluating diagnostic and therapeutic products
- Office of Rare Diseases Research, which coordinates and supports rare diseases research
- Components of the Molecular Libraries, which is an initiative that provides researchers with access to the large-scale screening capacity necessary to identify compounds that can be used as chemical probes to validate new therapeutic targets
- Therapeutics for Rare and Neglected Diseases, which is a program to encourage and speed the development of new drugs for rare and neglected diseases

The budget for NCATS is primarily a reallocation of funds from programs previously located in the NIH Office of the Director, National Human Genome Research Institute, and National Center for Research Resources. NIH is committed to both basic and applied research and has maintained a relatively stable ratio of funding across these two areas of focus. The funding ratio will not be disturbed by the establishment of this new center.

The formation of NCATS has been a methodical process highlighted by the recommendation of the NIH Scientific Management Review Board in December 2010 to create a new center dedicated to advancing translational science. This recommendation was followed by a year of intensive feedback and expert insight from all sectors of translational science through advisory meetings and extensive public consultation.

"I am deeply grateful for the expertise and insight provided by the many researchers, industry executives, patients, voluntary organizations, and NIH staff that helped NIH evaluate NCATS' purpose and crystallize its vision," said Dr. Collins.

To learn more about the impetus and development of NCATS, go to:

- NCATS web page: *www.ncats.nih.gov*
- NCATS on the Feedback NIH website: *http://feedback.nih.gov/index.php/category/ncats* ■

Kidney Interagency Coordinating Committee Meets to Discuss Quality Improvement in Care for Dialysis Patients

The National Kidney Disease Education Program (NKDEP), a service of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), hosted a meeting of the Kidney Interagency Coordinating Committee (KICC) in September 2011 on the campus of the National Institutes of Health in Bethesda, MD.

"Why measure quality? One answer is to drive improvement. Having the quality of your performance measured acts as an incentive for health care providers."

Shari Ling, M.D.,
Deputy Chief Medical Officer, Centers for Medicare and Medicaid Services

Andrew S. Narva, M.D., F.A.C.P., director of the NKDEP, opened with a review of KICC's history and its goals. KICC was founded in 1983 to help agencies in the Federal Government coordinate their efforts on kidney disease.

Dr. Narva introduced two guest speakers from the Centers for Medicare and Medicaid Services (CMS), as the focus of the day's meeting would be discussing the role of federal agencies in improving quality of care.

The speakers, Kimberly Smith, M.D., M.S., and Shari Ling, M.D., represented CMS's Office of Clinical Standards and Quality (OCSQ).

CMS Goals

Dr. Smith spoke first, saying that the CMS is trying to shift from a system of payment for quantity of health care services to a system of payment for quality of health care services and better outcomes.

She presented the CMS goals, including

- Better care: Improve the overall quality, by making health care more patient-centered, reliable, accessible, and safe.
- Healthy people: Improve the health of the U.S. population by supporting proven interventions to address behavioral, social, and environmental determinants of health in addition to delivering higher-quality care.
- Affordable care: Reduce the cost of quality health care for individuals, families, employers, and Government.

Dr. Smith clarified that "healthy people" refers to the prevention of disease and that "affordable care" was not to be interpreted as rationing.

Dr. Smith reported that a recent initiative of the OCSQ is the ESRD Quality Incentive Program (QIP), the first in a series of CMS programs that mark a significant change in how Medicare reimburses providers and facilities for patient care. CMS developed the ESRD QIP to be the nation's first pay-for-performance, also known as "value-based purchasing," program as mandated by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Along with the ESRD QIP, MIPPA also created a new payment system to replace a payment system in effect since 1983. The "composite rate" under the old system included some drugs, laboratory tests, and supplies. Over time, the expenditures for separately billable drugs, for example, erythropoeisis-stimulating agents and vitamin D analogues, have increased substantially. They now constitute 40 percent of total Medicare spending for outpatient dialysis.

Dr. Smith emphasized that the CMS is eager to collaborate with other agencies to deal with issues of quality improvement in the delivery of dialysis services.

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Measuring the Quality of Dialysis Services

Dr. Ling gave a presentation on the challenges of measuring the quality of dialysis services.

She asked, "Why measure quality? One answer is to drive improvement. Having the quality of your performance measured acts as an incentive for health care providers. Measurement provides information about whether goals are being met."

Dr. Ling discussed three types of measurement: process, outcomes, and composite.

According to Dr. Ling, the two most commonly used are process and outcome measures. Process measures look at whether the appropriate processes are used to deliver the care. These types of measures are often favored by the health care community because they are within the control of the organization or clinician. Process measures are not usually risk adjusted. Instead they rely on the use of exclusions and the stratification of results by patient characteristics. Outcomes measure the end result and can be influenced by many factors, including patient factors. For this reason, they require risk adjustment.

Composite measures are usually created to look at how well a more comprehensive set of related processes of care are delivered and provide more insight into the quality of care delivered for a particular health condition. Combining measures can make it easier for users to quickly interpret the information.

A critical aspect of measure development is identifying appropriate data sources. Currently, claims data are being used to assess most measures, which does not allow for proper measurement. Implementation of CROWNWeb, the CMS electronic health record system, will improve measurement.

The measurement development process provides ample opportunity for involvement across federal agencies. CMS is already collaborating with the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention (CDC), and the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation.

Discussion

Drs. Smith and Ling proposed a series of questions to members of the committee:

- How do you create quality measures for ESRD treatments?
- Which data sources should be considered to evaluate the feasibility of a quality measurement?
- How do you implement an incentive program that encourages quality improvement?

The members of the committee raised additional questions.

- How do you translate measurements into better outcomes?
- What data sources can be used to measure improvement at the population level?

Robert A. Star, M.D., director of NIDDK's Division of Kidney, Urologic, and Hematologic Diseases, asserted that care for chronic kidney disease (CKD) patients before dialysis is critical to quality improvement. The measures for fistula preparation, education, and predialysis medical care are needed. He also raised the question, "How do we address the high mortality rate of patients in the first 6 months of dialysis?"

Drs. Smith and Ling repeated their invitation for other agencies represented at the KICC meeting to become involved in the quality improvement and measurement development process.

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NKDEP Coordinating Panel Meeting Focuses on Translational Research

On November 3, 2011, the National Kidney Disease Education Program (NKDEP) Coordinating Panel met in Bethesda, MD, to review recent program achievements and discuss new directions for the NKDEP to pursue.

NKDEP
National Kidney Disease Education Program

The NKDEP is an initiative of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health, U.S. Department of Health and Human Services. The NKDEP aims to raise awareness of the seriousness of kidney disease, the importance of testing those at high risk, and the availability of treatment to prevent or slow kidney disease. The panel is made up of representatives from national foundations, patient advocacy groups, professional organizations, and Government agencies with a focus on kidney disease.

The morning session consisted of a panel presentation and discussion on translational research that will inform NKDEP goals and programs. Members of the panel were recipients of grants designed to support research that can discover ways to raise patient and provider awareness of kidney disease and foster positive behaviors. Andrew S. Narva, M.D., F.A.C.P., director of the NKDEP, explained that the grants program provided an opportunity for collaboration between the NKDEP and the research community as well as a way to translate research findings into action.

Neil Powe, M.D., M.P.H., M.B.A., of the University of California, San Francisco, described his department's study that will use health information technology (IT) to enhance primary care for chronic kidney disease (CKD) patients in community health clinics. The study will use social cognitive theory to help meet behavioral targets in the care of CKD patients. The study will introduce an automated CKD registry incorporating decision support, which will identify patients with CKD, send notifications to providers, and provide educational materials to patients and providers. "This proposal unites a large safety-net health system for patients at high risk for CKD to address barriers to improved CKD management," said Dr. Powe. "Successful interventions can be extended throughout our larger healthcare system, on a wider scale in similar safety-net systems."

Miguel Vazquez, M.D., of the University of Texas Southwestern Medical Center at Dallas, described his study designed to improve CKD detection and care in a high-risk, underserved population. The study will use an IT-enabled program to harness the electronic medical record to implement, coordinate, and monitor evidence-based interventions in the patient population. Vazquez concluded, "Successful application of this collaborative primary care/nephrology model of care, which incorporates new health information technology, has the potential to improve the care not only for minority patients in our institution but for all CKD patients in the United States."

L. Ebony Boulware, M.D., M.P.H., F.A.C.P., of The Johns Hopkins University reported on her organization's study using decision support interventions to improve renal replacement therapy—dialysis, transplantation, or conservative management. The study promotes shared,

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informed decision-making between the patient and the health care provider, so the patient will be better prepared for dialysis, transplantation, or conservative management when the time comes. "Many patients with kidney disease require renal replacement therapy," said Dr. Boulware. "But studies show patients are often psychologically and physically unprepared for renal replacement therapy, which leads to their poor health outcomes. This project aims to help patients with chronic kidney disease get better prepared for starting renal replacement therapy."

Katherine Tuttle, M.D., of the Providence Sacred Heart Medical Center and Children's Hospital in Spokane, WA, described her organization's study of a plan to provide information about medications to hospitalized patients with CKD. A requirement of the program is that the patient receive a home visit from a pharmacist within 5 days of hospital discharge. "This medication information transfer intervention in the transitional care of hospitalized CKD patients will have wide appeal for adoption by health care systems and for other chronic illnesses," said Dr. Tuttle. "The project supports the mission of NIDDK by translating lessons learned from clinical research in CKD into improved clinical outcomes that can be readily measured and anticipated in practice."

Joseph Nally, M.D., of the Cleveland Clinic, reported on his organization's study designed to help patients navigate the challenges of having CKD. The program features the use of a CKD patient navigator, a person who helps the patient understand instructions from health care providers and follow those instructions. The program will also use an existing electronic personal health record (PHR) system to use electronic communication to disseminate CKD education and stage-specific goals of care for patients with moderate to severe CKD. Dr. Nally explained, "We hypothesize that an enhanced PHR will result in a more informed, activated patient than usual care."

In the afternoon, members of the NKDEP staff reported on the program's activities and accomplishments over the past year. Eileen Newman, M.S., R.D., reported on the NKDEP's collaboration project with the Academy of Nutrition and Dietetics—formerly the American Dietetic Association—to produce five education modules to help general practice registered dietitians provide effective medical nutrition therapy (MNT) to CKD patients who are not on dialysis. The purpose of MNT for CKD is to maintain good nutritional status, slow progression, and treat complications. These materials are designed to distill key information about CKD and diet for registered dietitians and patients. In addition to the training modules for registered dietitians, which can be taken for continuing education units through the Academy of Nutrition and Dietetics, the nutrition project has produced a series of seven patient education fact sheets to help patients understand food labels, lab test results, and the importance of various nutrients, including protein, sodium, phosphorus, and potassium.

Newman reported that the NKDEP is conducting research to lay the groundwork for a Hispanic outreach campaign. Current efforts include looking at existing CKD materials in Spanish and exploring the possibility of using social media. Based on existing English brochures, the NKDEP has prepared two brochures in Spanish that have been adapted to appeal to a Hispanic/Latino audience.

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Care for Dialysis Patients, continued from page 13

Agency Updates

Near the end of the meeting, committee members had an opportunity to report on their agencies' activities. Christine Chang, M.D., M.P.H., informed the committee that the Agency for Healthcare Research and Quality will release a report on screening and monitoring for CKD. A portion of this report was used by a task force to develop screening recommendations, which will be released in 2012. The agency may allow for a public comment period on these recommendations. An upcoming report on biomarkers for management of anemia in predialysis and dialysis patients will soon be coming out for public comment.

Desmond Williams, M.D., Ph.D., reported that the CDC has received funding for its CKD surveillance website for the next 5 years.

Dr. Narva closed the meeting, thanking attendees for their participation. ■

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The NKDEP will be expanding and enhancing its outreach to the African American community. Recently, Griffin P. Rodgers, M.D., M.A.C.P., director of the NIDDK, and Dr. Narva embarked on a national radio media tour of the South, a region that has been hit hard by CKD and kidney failure, to raise awareness of CKD.

Dr. Narva announced that the NKDEP's Laboratory Working Group has had success in its mission to standardize laboratory assessment of CKD, particularly in the area of reporting glomerular filtration rate (GFR), a measure of how well the kidneys are working. Dr. Narva noted that many laboratories are not using the latest, most reliable equation for calculating GFR.

At the close of the meeting, Dr. Narva encouraged attendees to visit the "Get Involved" page on the NKDEP website at *nkdep.nih.gov/get-involved.shtml*. The page contains links to clinical tools, patient education materials, community outreach resources, and images that can be downloaded and used in educational presentations. ■

NIDDK Scientific Director Ira Levin Retires

From NIH Record
By Rachel Greenberg

NIDDK Scientific Director Ira Levin, Ph.D. (center) is honored by NIDDK Director Griffin P. Rodgers, M.D., M.A.C.P. (at podium) at a celebration in honor of Levin's retirement from the NIH after 48 years of Government service.

When Dr. Ira Levin, a world leader in vibrational spectroscopy and NIDDK scientific director since 2009, retired from NIH recently, he left a huge mark, both on his field and on NIH. In nearly 48 years at NIH, Levin's career included 235 publications, 135 published meeting abstracts and 20 awards and honors, including the Pittsburgh Spectroscopy Award, the top award in the field.

"You want to carry on your most creative, innovative and strongest research. Maintain the enthusiasm of the enterprise and do it all by remaining invisible."

Ira Levin, Ph.D.
former NIDDK Scientific Director

"For the past 48 years, Ira's work has focused on developing new and innovative spectroscopic methods and their applications to a wide range of problems," said Dr. William Eaton, chief of NIDDK's Laboratory of Chemical Physics. "From his early work initiating the field of infrared imaging, to using both infrared and Raman measurements to characterize the structure of lipid bilayer systems, and to his latest work applying vibrational spectroscopic imaging to medical diagnostics, Ira has been the acknowledged leader and among the most cited spectroscopists of his generation."

Levin's scientific career was matched, if not exceeded, by the strong relationships and accolades that marked his administrative roles at NIDDK. Levin's colleagues described their mentor as the "captain of their ship," saying he will be much missed.

"Ira is the epitome of modesty and unpretentiousness," said NIDDK director Dr. Griffin Rodgers. "When he popped in on scientists and staff he was a colleague and mentor—not the 'scientific director.' I will miss Ira's gracious guidance and insights, his love for science and his support for the people behind the science."

"If NIDDK had an award for 'mensch laureate,' Ira would be the leading candidate for that award," said Dr. James Balow, NIDDK clinical director. Balow will serve as acting scientific director until a new SD is named.

Since the mid-1990s, Levin held several management positions with the NIDDK Division of Intramural Research while continuing to lead the molecular biophysics section of the Laboratory of Chemical Physics until 2009.

"The same talents you hone over the years as a scientist work well for an administrator," said Levin. "I'd listen carefully, go to meetings, hear others' ideas and then flesh out new thoughts."

Balow explained his colleague's administrative success otherwise. "I'm convinced that Ira's mastery of fine spectral signal discrimination formed the underpinnings and created the model for his success," said Balow. "Ira could detect the key elements resounding from the chorus of requests and competing interests of his constituents in NIDDK. He was a master at separating the wheat from the chaff, the frivolous from the important."

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Brown Medicine Magazine Profiles NIDDK Director Griffin P. Rodgers

Excerpted from Brown Medicine
By Sarah Baldwin-Beneich and David Peterson

Brown Medicine magazine featured Griffin P. Rodgers, M.D., M.A.C.P., director of the National Institute of Diabetes and Digestive and Kidney Diseases, on the cover of its Fall 2011 issue. Read an excerpt from the story, "The Ambassador," below:

"I saw that diabetes, obesity, and kidney disease hit African Americans harder than others. This was my first exposure to the effects and interaction of genetics and the environment."

Griffin P. Rodgers, M.D., M.A.C.P.
NIDDK Director

A hematologist by training, Rodgers first became interested in medicine growing up in the '60s and '70s in New Orleans. He excelled in math and science early on. His father taught physical education and science. But it was his mother, a public health nurse, who first exposed him to the practice and potential of medicine.

"Many of my mother's patients weren't able to get to the clinic during the work week. She'd take it upon herself to visit them at their homes during the weekend. We went to some rough neighborhoods," Rodgers recalls, laughing softly, "and she took me along as protection." He watched as she applied her nursing training and practical approaches to solve medical problems.

"I learned quite a bit this way. Her knowledge, compassion, and ability to get along with people went a long way in getting them to follow instructions, do follow-up."

Making the rounds with his mother was formative in another sense, as well: "I saw that diabetes, obesity, and kidney disease hit African Americans harder than others. This was my first exposure to the effects and interaction of genetics and the environment."

For more information or to read the full article, visit the *Brown Medicine* magazine website at *www.brownmedicinemagazine.org/index.php.* ■

Levin Retires, continued from page 17

Levin's ability to distribute resources fairly in the face of shrinking budgets earned the respect of his colleagues and supervisors alike.

"In his unswerving dedication and commitment to NIDDK, Ira exhibited a deep understanding of the concept of the common good," said Balow. "His decisions were based on what was good for NIDDK as a whole, and ultimately, the good of the public, which entrusts us with its treasure chest of support."

Reflecting on his career at NIDDK, Levin said he was most proud of his colleagues' passion and intellect, their readiness to exchange ideas and the outstanding ratings NIDDK received from the board of scientific counselors. Of himself, he said, "As administrator, you want to carry on your most creative, innovative and strongest research. Maintain the enthusiasm of the enterprise and do it all by remaining invisible."

Fortunately for NIH and the field of spectroscopy, Levin's influence was anything but invisible. ■

NIDDK Advisory Council Member Receives 2011 Physician Clinician in Diabetes Award

Adapted from the University of Washington Office of News and Information

Dr. Jerry P. Palmer, professor of medicine, has received the American Diabetes Association's prestigious 2011 Outstanding Physician Clinician in Diabetes Award. The award was presented at the Association's 71st Scientific Sessions in San Diego, Calif.

Dr. Jerry P. Palmer

The Outstanding Physician Clinician in Diabetes Award is given to an individual who has made major contributions to diabetes care as a widely respected clinician and educator.

Palmer is a member of the Advisory Council of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and is the director of the UW Diabetes Endocrinology Research Center and chief of the Division of Endocrinology, Metabolism, and Nutrition, Puget Sound Veterans Affairs Health Care System. Palmer has a distinguished career as clinician, educator, mentor, and scientist.

Known internationally for his discovery of insulin autoantibodies, Palmer also is highly regarded locally as a clinician, in part because he implements research findings to help patients.

Palmer was a principal investigator of the Seattle Diabetes Control and Complications Trial (DCCT) site. Realizing the importance of the multidisciplinary approach, he created the UW Diabetes Care Center. This clinic has an international reputation as a premier academic diabetes center. Palmer is also a clinician and teacher in the Puget Sound Veterans Affairs Health Care System's Endocrine Clinic, a popular training site for UW students, residents and fellows.

Palmer is a past recipient of the Robert H. Williams Rachmiel Levine Award and has been repeatedly named among the Best Doctors in America. He is a past president of the Immunology of Diabetes Society.

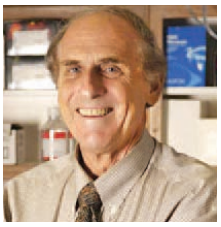
He has served on the board of the American Diabetes Association's Washington affiliate (1975-1983), and on its national board (1994-1997). He was on the National Institutes of Health steering committee for the Diabetes Prevention Trial–Type 1 (DPT-1) and now for Type 1 Diabetes TrialNet, and is on the international executive committee for TRIGR (Trial to Reduce Insulin Dependent Diabetes in the Genetically at Risk). ■

NIH Grantees Win 2011 Nobel Prize in Physiology or Medicine

From NIH News


Bruce A. Beutler, M.D.


Jules A. Hoffmann, Ph.D.


Ralph M. Steinman, M.D.

The 2011 Nobel Prize in Physiology or Medicine has been awarded to National Institutes of Health grantees Bruce A. Beutler, M.D., of The Scripps Research Institute, La Jolla, Calif., and Jules A. Hoffmann, Ph.D., for their discoveries concerning the activation of innate immunity; and the late Ralph M. Steinman, M.D., of Rockefeller University, New York City, for his discovery of the dendritic cell and its role in adaptive immunity.

"Their discoveries have opened up the possibility of harnessing the body's own cells and immune processes to prevent infectious diseases, autoimmune disorders, allergic diseases, cancer, and rejection of organ transplants."

Anthony S. Fauci, M.D.
NIAID Director

"The work of these three NIH-supported scientists has provided fundamental understanding of the body's immune system, and has been pivotal to the development of new vaccines against infectious diseases and treatments for cancer," said NIH director Francis S. Collins, M.D., Ph.D.

The NIH began supporting the work of Dr. Beutler in 1984 and has provided almost $58 million in support. Dr. Beutler's work has been supported by the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of General Medical Sciences, and the National Cancer Institute. Dr. Hoffmann has received almost $7 million in support from NIAID since 1998. NIAID began supporting the work of Dr. Steinman in 1976 and provided more than $49 million in support.

"NIAID has had the honor of supporting all three awardees," says NIAID Director Anthony S. Fauci, M.D. "Their elegant work has been — and will continue to be — extraordinary in its impact. It is rare that an investigator makes a discovery so important that it influences virtually every aspect of a scientific discipline. Their discoveries have opened up the possibility of harnessing the body's own cells and immune processes to prevent infectious diseases, autoimmune disorders, allergic diseases, cancer, and rejection of organ transplants."

The Office of the Director, the central office at NIH, is responsible for setting policy for NIH, which includes 27 Institutes and Centers. This involves planning, managing, and coordinating the programs and activities of all NIH components. The Office of the Director also includes program offices which are responsible for stimulating specific areas of research throughout NIH.

Additional information is available at *www.nih.gov/icd/od.* ■

NIH Clinical Center Receives 2011 Lasker~Bloomberg Public Service Award

Adapted from NIH News

John I. Gallin, M.D., director of the NIH Clinical Center (second from left), accepts the 2011 Lasker~Bloomberg award on behalf of the Clinical Center and the NIH.

The NIH Clinical Center, the clinical research hospital at the National Institutes of Health in Bethesda, Md., is the 2011 recipient of the Lasker~Bloomberg Public Service Award. The award was presented by the Albert and Mary Lasker Foundation, which has recognized outstanding advances in medical research each year since 1945. The award honors the Clinical Center for serving as a model institution that has transformed scientific advances into innovative therapies and provided high-quality care to patients.

"The NIH Clinical Center has been pivotal in advancing clinical studies that are at the forefront of solving the nation's most pressing public health issues."

Griffin P. Rodgers, M.D., M.A.C.P.
NIDDK Director

The award recognizes the Clinical Center's rich history of medical discovery through clinical research since it opened in 1953. Over the decades, nearly half a million volunteers have participated in clinical research at the Clinical Center. Its mission has remained providing exceptional clinical care for research volunteers, an environment for innovative bench-to-bedside clinical research, and training for clinical researchers.

"The Clinical Center, the world's largest clinical research hospital, exists to help scientists who are clinicians rapidly translate promising discoveries in the laboratory into new and better ways to treat and prevent disease," said NIH Director Francis S. Collins, M.D., Ph.D. "The Clinical Center's 58-year research portfolio has resulted in remarkable medical advances."

Those medical milestones include development of chemotherapy for cancer; the first use of an immunotoxin to treat a malignancy (hairy cell leukemia); identification of the genes that cause kidney cancer, leading to the development of six new, targeted treatments for advanced kidney cancer; the demonstration that lithium helps depression; the first gene therapy; the first treatment of AIDS (with AZT); and the development of tests to detect AIDS/HIV and hepatitis viruses in blood, which led to a safer blood supply.

"By enabling some of the world's top medical researchers to collaborate in innovative, interdisciplinary ways, the NIH Clinical Center has been pivotal in advancing clinical studies that are at the forefront of solving the nation's most pressing public health issues," said Griffin P. Rodgers, M.D., M.A.C.P., director of the National Institute of Diabetes and Digestive and Kidney Diseases.

"The Clinical Center's work has always depended on patients and healthy individuals from around the world who volunteer for clinical research here," said John I. Gallin, M.D., director of the NIH Clinical Center. "Our patients include those with rare diseases, common disorders, and undiagnosed conditions. There are about 1,500 clinical research studies under way today and the patients and healthy volunteers who participate in them are true partners in research."

Advancements through clinical research also depend on having a cadre of investigators trained to do it, Gallin added. "Students in the health sciences and clinicians come here to learn how to conduct clinical research by working closely with NIH investigators. Since 1995, more than 22,000 students around the world have

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Former NIH Director Healy Dies at 67

From NIH Record

Bernadine P. Healy, M.D.

Dr. Bernadine Healy, who became the 13th NIH director in April 1991 and was the first woman to head the agency, died in 2011 at age 67. She had battled brain cancer for 13 years.

"How wonderful to be in a career that in almost any dimension of it—whether you're the doctor at the bedside, or the scientist in the laboratory … that you are doing something that is pure in its fundamental purpose, which is helping another human being."

Bernadine P. Healy, M.D.
Former NIH Director

Healy served as NIH director for 2 years, during which she launched the $625 million Women's Health Initiative and established the Shannon Awards, which fostered innovative approaches in research. She also established a policy that all NIH-funded clinical trials on conditions that affect both genders must include both men and women.

"I am deeply saddened by the death of former NIH Director Bernadine P. Healy, and will greatly miss her courageous leadership on behalf of biomedical research," said NIH director Dr. Francis Collins. "Dr. Healy will be long remembered for her visionary efforts that transformed the landscape of women's health research."

Healy came to NIH from the Cleveland Clinic Foundation, where she had been a research director and cardiologist for 6 years. She had also been deputy director of the Office of Science and Technology Policy at the White House and a professor of medicine at Johns Hopkins University.

Healy was president of the American Heart Association in 1988-1989 and was a member of the Institute of Medicine. A native of Queens, N.Y., she had earned her medical degree at Harvard Medical School.

After leaving NIH, she was dean of Ohio State University Medical School (1995-1999) and president and chief executive officer of the American Red Cross (1999-2001). She was also a columnist for *U.S. News & World Report*. In 1994, she ran unsuccessfully for the U.S. Senate from Ohio.

Collins, whom Healy recruited from the University of Michigan to head the nascent Human Genome Project at NIH, said, "I will be forever grateful to Dr. Healy for her vigorous support of the public effort to sequence the human genome and her keen insights into the potential of genomic research for revolutionizing medicine."

In remarks she made for an NIH exhibit on pioneering women doctors, Healy said, "All of us, I believe, in our hearts are humanitarian. And how wonderful to be in a career that in almost any dimension of it—whether you're the doctor at the bedside, or the scientist in the laboratory, or the public health doc tracking down the latest epidemic—that you are doing something that is pure in its fundamental purpose, which is helping another human being."

Healy is survived by her husband, Dr. Floyd D. Loop, and two daughters. ■

NIH Center Receives Award, continued from page 21

participated in the Clinical Center's clinical research training curriculum offered through distance-learning programs."

The original hospital, the Warren Grant Magnuson Clinical Center, opened in 1953. A new research hospital, the 240-bed Mark O. Hatfield Clinical Research Center, opened in 2004. Most of NIH's 27 institutes and centers conduct clinical research at the Clinical Center through their programs on the NIH campus in Bethesda, Md. NIH plans to open the facility for use by external researchers, based on the 2010 recommendations from the Scientific Management Review Board, established under the NIH Reform Act of 2006, which will allow the Clinical Center to facilitate clinical research on a broader scale.

For more information, visit the NIH Clinical Center at *http://clinicalcenter.nih.gov.* ■

Updated Publications

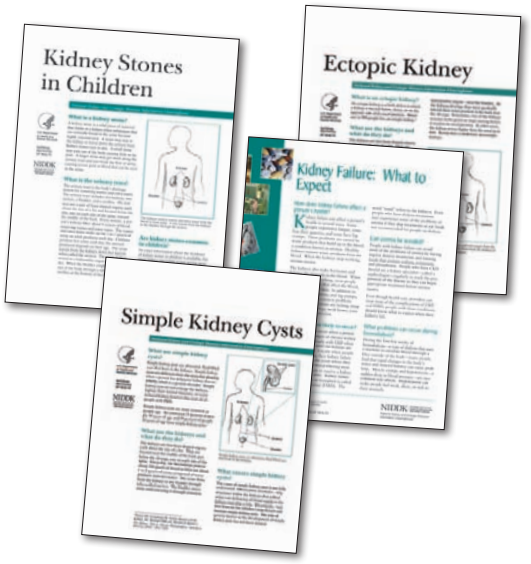
The National Kidney and Urologic Diseases Information Clearinghouse (NKUDIC) has published the following new fact sheet:

- *Kidney Stones in Children*

The NKUDIC has updated the following publications:

- *Ectopic Kidney*
- *Kidney Failure: What to Expect*
- *Simple Kidney Cysts*

These publications are available at *www.kidney.niddk.nih.gov*.



Upcoming Meetings, Workshops, and Conferences

The National Institute of Diabetes and Digestive and Kidney Diseases Information Clearinghouses will exhibit at the following upcoming events:

American Urological Association 2012 Annual Meeting

May 19–23 in Atlanta.
For more information, visit *www.aua2012.org*.

American Academy of Nurse Practitioners 27th National Conference

June 20–24 in Orlando.
For more information, visit *www.aanp.org*.

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